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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,795	06/27/2003	Mansukh C. Wani	195805US77	5879
22850	7590	07/12/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			DESAI, RITA J	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 07/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/606,795	WANI ET AL.	
	Examiner	Art Unit	
	Rita J. Desai	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 12-20 is/are rejected.
- 7) ☒ Claim(s) 1-8 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>6/24/04</u> . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/29/03</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, 12-20 in part, drawn to compounds and method of making the compounds of formula I, classified in class 546, subclass 41.
- II. Claims 1, 2, 9-11, 12-20 in part, drawn to compounds and method of making compounds of formula II, classified in class 546, subclass 48.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have a different core structure one, has a pentacyclo core and the other has a hexacyclo core. The bonding and properties are different.

And when a preliminary search on a core was done it gave numerous iterations indicating that the core is not the applicants contribution over the prior art.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

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During a telephone conversation with Mr. Derreck Mason on 6/ 23/04 a provisional election was made with traverse to prosecute the invention of Group I , claims 1-8, 12-20 drawn to compounds and method of making compounds of formula I. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-11 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicants preserve their right to file a divisional on the cancelled non-elected claims , without prejudice in due course.

If applicant 's traverse on the grounds that the inventions are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art , the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

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Claim Objections

Claim 1 is objected to because of the following informalities: The connection of X group to the ring is not clearly shown in the formula I. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

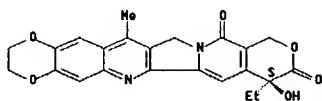
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Walter loos et al Structural identification and ... March 2002.

The reference clearly discloses the compounds of the claims .

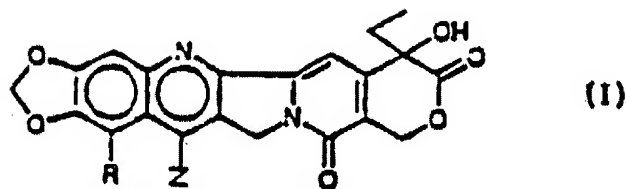
See page 857 fig. 1.



Claims 12-20 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9104260 Wall Monroe et al

The reference discloses the compounds of the invention . See the whole document.

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Where in Z is a H or an alkyl group.

And R is NO₂ or NH₃ etc.

A camptothecin analog having structures (I) or (II), where Z is H or C₁₋₈ alkyl and R is NO₂, NH₂, N₃, hydrogen, halogen, COOH, OH, O-C₁₋₃ alkyl, SH, S-C₁₋₃ alkyl, CN, CH₂NH₂, NH-C₁₋₃ alkyl, CH₂-NH-C₁₋₃ alkyl, N(C₁₋₃ alkyl)₂, CH₂N(C₁₋₃ alkyl)₂, O-, NH- or S-CH₂CH₂N(CH₂CH₂OH)₂, O-, NH- or S-CH₂CH₂CH₂N(CH₂CH₂OH)₂, O-, NH- or S-CH₂CH₂N(CH₂CH₂CH₂OH)₂, O-, NH- or S-CH₂CH₂CH₂N(CH₂CH₂CH₂OH)₂, O-, NH- or S-CH₂CH₂CH₂N(C₁₋₃ alkyl)₂, O-, NH- or S-CH₂CH₂CH₂N(C₁₋₃ alkyl)₂, CHO, C₁₋₃ alkyl or NHCOCHR¹NR²R³, where R¹ is the side-chain of an α-ami-

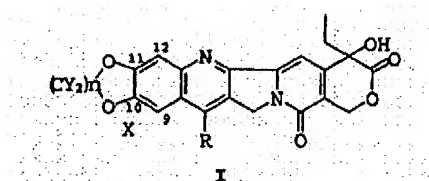
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 910426) and US 6143891 Fang et al.

The instant invention is drawn to compounds of the formula I where in X and R are various substituents.



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X is H, NH₂, H, F, Cl, Br, O-C₁₋₆ alkyl, S-C₁₋₆ alkyl, NH-C₁₋₆ alkyl, N(C₁₋₆ alkyl)₂, or C₁₋₃ alkyl,

or X is -Z-(CH₂)_a-N-(C₁₋₆ alkyl)₂ wherein Z is selected from the group consisting of O, NH and S, and a is an integer of 2 or 3,

or X is -CH₂NR²R³, where (a) R² and R³ are, independently, hydrogen, C₁₋₆ alkyl, C₃₋₇ cycloalkyl, C₃₋₇ cycloalkyl-C₁₋₆ alkyl, C₂₋₆ alkenyl, C₁₋₆ alkoxy-C₁₋₆ COR⁴ where R⁴ is hydrogen, C₁₋₆ alkyl, C₃₋₇ cycloalkyl, C₃₋₇ cycloalkyl-C₁₋₆ alkyl, C₂₋₆ alkenyl, C₁₋₆ alkoxy, C₁₋₆ alkoxy-C₁₋₆ alkyl, or (b) R² and R³ taken together with the nitrogen atom to which they are attached form a saturated 3-7 membered heterocyclic ring which may contain a O, S or NR⁵ group, where R⁵ is hydrogen, C₁₋₆ alkyl, alkyl, aryl, aryl substituted with one or more groups selected from the group consisting of C₁₋₆ alkyl, amino, C₁₋₆ alkylamino, C₁₋₆ alkoxy, C₁₋₆ alkoxy-C₁₋₆ alkyl, C₁₋₆ alkyl, C₁₋₆ alkoxy, aryl, and aryl substituted with one or more C₁₋₆ alkyl, or C₁₋₆ alkoxy-C₁₋₆ alkyl groups;

R is C₁₋₃₀ alkyl, substituted C₁₋₃₀ alkyl, C₁₋₃₀ alkenyl, substituted C₁₋₃₀ alkenyl, C₁₋₃₀ alkynyl, substituted C₁₋₃₀ alkynyl, C₃₋₃₀ cycloalkyl, substituted C₃₋₃₀ cycloalkyl, C₆₋₁₈ aryl,

Scope and Content of Prior Art

WO 910426 discloses similar compounds with various R and Z substituents.

US 6143891 Fang et al also generically discloses the dioxo hexacyclo camptothecin analogs.

It also teaches that its R1 and R2 substituents represent numerous different groups and both are same or different.

Thus indicating the equivalence of the position.

Prima Facie Obviousness

Thus according to the teaches of Fang et al one of skill in the art would find it obvious to make various compounds of WO '426 with different Z and R groups.

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Conclusion

The method of making these compounds claims 1-8 are however found to be allowable since the prior art neither teaches or anticipates using the amino cyano reactant of formula III with compounds of formula VII to obtain the compounds of formula I.

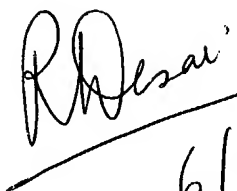
The closest art shows using the aldehyde form .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

R.D.
June 24, 2004

Rita J. Desai
Primary Examiner
Art Unit 1625

6/24/04